

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: )  
)  
Gerald W. FISCHER et al. ) Group Art Unit: Not yet assigned  
)  
Serial No.: Not yet assigned ) Examiner: Not yet assigned  
(Previous serial no.: 09/097,055) )  
)  
Filed: June 29, 2001 )  
(Previous filing date: June 15, 1998) )  
)  
For: OPSONIC AND PROTECTIVE )  
MONOCLONAL AND CHIMERIC )  
ANTIBODIES SPECIFIC FOR )  
LIPOTEICHOIC ACID OF GRAM )  
POSITIVE BACTERIA )

Assistant Commissioner for Patents  
Washington, DC 20231

Sir:

**PRELIMINARY AMENDMENT**

Prior to the examination of the above application, please amend this application as follows:

**IN THE SPECIFICATION:**

At page 2, replace the paragraph beginning at line 2 with the following new paragraph:

This application claims the benefit of Provisional Application Serial No. 60/049,871, filed June 16, 1997, which application is specifically incorporated herein by reference. The following applications, listed by serial number and filing date, contain material pertaining to this application: 08/458,418 filed on June 2, 1995; 08/472,716 filed on June 6, 1995; and 08/471,285 filed on June 6, 1995.

At page 8, replace the paragraph beginning on line 19 with the following new paragraph:  
Figure 12 (SEQ ID NOS 86-89, respectively) provides the final consensus DNA sequence of the heavy and light chain variable regions.

At page 71, at the end of the specification, before the claims, delete the previously filed Sequence Listing and insert the printed Sequence Listing submitted herewith.

**IN THE CLAIMS:**

Please renumber claim pages 122-129 sequentially after the Sequence Listing submitted concurrently herewith.

Please cancel claim 1 and add new claims 32-44 as follows:

32. A method for treating or preventing an infection caused by Gram positive bacteria in a patient comprising administering to the patient a therapeutically or prophylactically effective amount of a pharmaceutical composition,

wherein the pharmaceutical composition comprises an antibody to lipoteichoic acid of Gram positive bacteria, or fragment, region, or derivative thereof, and a pharmaceutically acceptable carrier, and

wherein the antibody, fragment, region, or derivative thereof

- (a) binds to lipoteichoic acid at a level that is twice background or greater, and
- (b) enhances the opsonization of Gram positive bacteria by 75% or more.

33. The method of claim 32, wherein the antibody is a monoclonal antibody.

34. The method of claim 33, wherein the monoclonal antibody is MAB 96-110.

35. The method of claim 34, wherein MAB 96-110 is chimeric and humanized.

36. The method of claim 32, wherein the antibody, fragment, region, or derivative thereof binds to a peptide sequence chosen from:

W R M Y F S H R H A H L R S P (SEQ ID NO: 1) and

W H W R H R I P L Q L A A G R (SEQ ID NO: 2).

37. A method for treating or preventing an infection caused by Gram positive bacteria in a patient comprising administering to the patient a therapeutically or prophylactically effective amount of a pharmaceutical composition,

wherein the pharmaceutical composition comprises an antibody to lipoteichoic acid of Gram positive bacteria, or fragment, region, or derivative thereof, and a pharmaceutically acceptable carrier, and

wherein the antibody, fragment, region, or derivative thereof bind to a peptide sequence chosen from:

W R M Y F S H R H A H L R S P (SEQ ID NO: 1) and

W H W R H R I P L Q L A A G R (SEQ ID NO: 2).

38. The method of claim 37, wherein the antibody is a monoclonal antibody.

39. The method of claim 38, wherein the monoclonal antibody is MAB 96-110.

40. The method of claim 39, wherein MAB 96-110 is chimeric and humanized.

41. A method for treating or preventing an infection caused by Gram positive bacteria in a patient comprising administering to the patient a therapeutically or prophylactically effective amount of a pharmaceutical composition,

wherein the pharmaceutical composition comprises a lipoteichoic acid epitope peptide mimic, and a pharmaceutically acceptable carrier, and

wherein the peptide mimic is a peptide sequence chosen from:

- (a) W R M Y F S H R H A H L R S P (SEQ ID NO: 1);
- (b) W H W R H R I P L Q L A A G R (SEQ ID NO: 2); and
- (c) peptide sequences that are substantially homologous to the sequences of (a) or (b).

42. A method for treating or preventing an infection caused by Gram positive bacteria in a patient comprising administering to the patient a therapeutically or prophylactically effective amount of a pharmaceutical composition,

wherein the pharmaceutical composition comprises a peptide encoded by DNA of the variable region of the anti-lipoteichoic acid antibody of Figure 12, or by a sequence that is at least 70% homologous to that DNA, and a pharmaceutically acceptable carrier.

43. A method for treating or preventing an infection caused by Gram positive bacteria in a patient comprising administering to the patient a therapeutically or prophylactically effective amount of a pharmaceutical composition,

wherein the pharmaceutical composition comprises a peptide characterized by amino acids corresponding to one or more of the Complementarity Determining Regions of the variable regions of the anti-lipoteichoic acid antibody of Figure 12, or amino acids that are at least 70% homologous to the Complementarity Determining Regions.

44. The method of claim 43, wherein the Complementarity Determining Regions are derived from MAB 96-110.

**IN THE DRAWINGS:**

Subject to the approval of the Examiner, please replace the current Figure 12 with the attached substitute Figure 12.

### REMARKS

Claims 32-44 are currently pending in this application. Applicants have submitted a substitute Figure 12 which underlines both those amino acid sequences present in the Complementarity Determining Regions (CDRs) of the heavy chain variable region and the light chain variable region. These underlined amino acids are those encoded by the CDR nucleic acid sequences which were originally underlined. As such, the content of the CDRs in Figure 12 has not been altered. Applicants have also consolidated the SEQ ID NOS of Figure 12 down to four SEQ ID NOS as shown in the table below.

New SEQ ID NO.	Previous SEQ ID NOS.	Identity of the Sequence
86	86, 88, 90, 92, 94	nucleic acid sequence of 96-110 heavy chain variable region
87	87, 89, 91, 93, 95	amino acid sequence of 96-110 heavy chain variable region
88	96, 98, 100, 102, 104	nucleic acid sequence of 96-110 light chain variable region
89	97, 99, 101, 103, 105	amino acid sequence of 96-110 light chain variable region

Support for this alteration in the sequence listing is found in the instant specification at page 58, lines 13-14; page 59, lines 8-9; and Figure 12 as originally filed. Pending claims 32-44 are based on claims 14-15 and 24-25 as originally filed. Applicants assert that pending claims 32-44 do not constitute issues of new matter.

If there is any fee due in connection with the filing of this Preliminary Amendment, please charge the fee to our Deposit Account No. 06-0916.

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Respectfully submitted,

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Dated: June 29, 2001

By: Jean B. Fordis  
Jean B. Fordis  
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APPENDIX TO PRELIMINARY AMENDMENT OF JUNE 29, 2001

Amendments to the Specification

At page 2, replace the paragraph beginning at line 2 with the following new paragraph:

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## FIGURE 12

96-110 anti-staph (HAY) heavy chain variable region (type IIIA)

R Y M L V H S G G G L V Q P X G Y L X L S C A A S C F T Y U  
 G A Y G T G A Y T G C T G C T G C G A G T T G C T G C A G C C T A A A C C G T C A T T T A A A C T C T C A T T G C A G C C T C G A T T C A C C T T C A A T

H T A H H W V R Q A P G X G L B H V A

B I R 9 K S H N Y A T F Y A D S V X D

C C C A T A A G A A G T A A A I A A T A T T C A A C X T P T A T T C C G G A T T C A G T C D A A G A G

[illegible][illegible]

96-110 anti-staph (HAY) light chain variable region (type VI)

Q I V L S Q S P A I L S A S P G H K V T H T C  
C A A " T C M C T C T C C A G T C T C T C T C A G C A Y C C T C A C A T C A C T C

0Y:05i:Y 2Y:4.1.YYY-1.5.1.0YYY2.1.50Y 2.0000Y

[illegible][illegible]

Y Y Q Q K P C S g P K P W I S A T S U L L A g

C G A V P Y N D S C S C G T J Y J L T I J N V E X B A X T Y Y C

CAGCAGCTGGAGTATGTAAACCCAGCCGCTCCGAGCCGCGGAGCTCCCTCCAAATACAA  
 530 TONG. 88

O O W S S H P P T P C C C T K L L R I R  
SEQ ID NO 89